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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,776	12/19/2005	Meir Shinitzky	74127JPW/JW	9387
23432 7590 09/22/2008 COOPER & DUNHAM, LLP 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036				
EXAMINER SHITERENGARTS, SAMANTHA L				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
09/22/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/530,776

Applicant(s)

SHINITZKY ET AL.

Examiner

Samantha L. Shterengarts

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-72 and 135-212 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 49-72 and 135-212 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 49-72 and 135-212 are currently pending in the instant application and are subject to a lack of unity requirement.

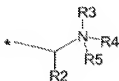
Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

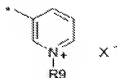
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I: Group I: Claims 49-57 and 64-72 (in part) drawn to methods for the treatment of inflammation comprising administering a compound of formula I wherein the residue A is of the formula below, as defined in claim 54.

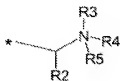


II: Group II: Claims 49-54, 58-60, and 64-72 (in part) drawn to methods for the treatment of inflammation comprising administering a compound of formula I wherein the residue A is phenyl, whose substitutions are defined in claim 54.

- III: Group III: Claims 49-54 and 61-72 (in part) drawn to methods for the treatment of inflammation comprising administering a compound of formula I wherein the residue A is of the formula below, as defined in claim 54.



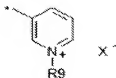
- IV: Group IV: Claims 135-149, 156-164, 186-197 and 204-212 (in part) drawn to a method of treating a T-cell mediated disease and a method of causing a shifting of T-cell cytokine response by administering a compound of formula Ia wherein the residue A is of the formula below, as defined in claim 142.



- V: Group V: Claims 135-142, 150-152, 156-164, 186-190, 198-200, and 204-212 (in part) drawn to a method of treating a T-cell mediated disease and a method of causing a shifting of T-cell cytokine response by administering a compound of formula Ia wherein the residue A is phenyl, whose substitutions are defined in claim 142.

- VI: Group VI: Claims 135-142, 153-164, 186-190, and 201-212 (in part) drawn to a method of treating a T-cell mediated disease and a method of causing a shifting of T-cell

cytokine response by administering a compound of formula Ia wherein the residue A is of the formula below, as defined in claim 142.



VII: Group VII: Claims 165-185 (in part) drawn to compounds of the general formula R1-O-CO-A wherein one of (i), (ii), (iii), or (iv), is true.

VIII: Group VIII: Claims 165-185 (in part) drawn to compounds of the general formula R1-O-CO-A wherein (v) is true.

IX: Group IX: Claims 165-185 (in part) drawn to compounds of the general formula R1-O-CO-A wherein (vi) is true.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13 which pertains to the Unity of Invention states that, "[t]he international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept." Furthermore, 37 CFR 1.475 part (b) states the following: "An international or a national stage application containing claims to different categories of invention

will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) *A* product and *a* process of use of said product; or...", emphasis added. Applicant's claims are drawn to **multiple** products (Groups VII, VIII, and IX) and **multiple** methods of using said products (Groups I thru VI).

The claims, therefore, lack unity of invention.

Accordingly, Groups I-IX are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept. Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical feature, the claims lack unity of invention and should be limited to only a product or a method of use. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Election of Species

3. As an additional requirement, with the election of any one of **Groups I-IX**, an election of species of a particular compound is also required. In order for this election to be considered fully responsive to this requirement the election **must include:**

Groups I-IX:

- a) the name and structure of the instantly claimed compound
- b) the location of the species (a) within the claims or (b) within the specification,

- c) the claims that read on the elected species,
- d) and a definition of the exact substitutions,
e.g. R₁ is Hydrogen, X is oxygen, etc...

Groups I-VI:

- a) a single disease or disorder to be treated

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

The examiner has required restriction between product and process claims. Where

applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samantha Shterengarts whose telephone number is (571)270-5316. The examiner can normally be reached on Monday thru Thursday 9-6pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samantha L. Shterengarts/ Examiner,
Art Unit 1626

/Kamal A Saeed, Ph.D./
Primary Examiner, Art Unit 1626